DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our Reference Numbers: 98-0889 and 98-0883

March 24, 1999

Pinya Cohen, Ph.D.
Nabi
P.O. Box 310701
Boca Raton, FL 33431-0701

Dear Dr. Cohen:

Your biologics license application for Hepatitis B Immune Globulin (Human) is approved effective this date. Nabi, Boca Raton, Florida, is hereby authorized to introduce or deliver for introduction into interstate commerce Hepatitis B Immune Globulin (Human) under Department of Health and Human Services U.S. License No. 1022.

Hepatitis B Immune Globulin (Human) is indicated for treatment of acute exposure to HBsAg, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure of infants to persons with acute HBV infection.

In accordance with approved labeling, your product will bear the trademark Nabi-HB™ and will be marketed in 1 mL and 5 mL fill sizes. Changes to the product, production process, location of production process, equipment, facilities, or responsible personnel are required to be reported to FDA as specified in Title 21 Code of Federal Regulations (CFR) Section 601.12.

The dating period for this product shall be 12 months from the date of manufacture when stored at 2-8 °C. The date of manufacture shall be defined as the date that the first sterile filtration of a uniform bulk is performed. Results of ongoing stability studies should be submitted throughout the dating period, as they become available.

We acknowledge the following actions you have committed to take following licensure of Hepatitis B Immune Globulin (Human):

1. The December 31, 1998 commitments to

   a) Validate pooling and shipment of plasma samples to [redacted] for polymerase chain reaction (PCR) testing;

   b) Validate effects of sample shipping and storage conditions on final container potency;

   c) [redacted]

   d) Develop an alternative (back-up) potency assay, and

e) Develop and validate an assay to discriminate between monomers and dimers in final containers.

2. [redacted]

3. The January 13, 1999 commitment to validate the refiltration process [redacted]

4. The February 17, 1999 commitment to include the acceptable ranges in IU/mL for [redacted] external reference standard materials.

5. The March 23, 1999 commitment to revise the Nabi-HB™ batch record to record the temperature of the product at the beginning and end of solvent/detergent treatment.

Annual updates on progress on post-marketing studies are requested to be submitted to FDA.

All adverse reports should be submitted according to 21 CFR 600.80 to the Center for Biologics Evaluation and Research (CBER), HFM-210, Food and Drug Administration, 1401 Rockville Pike, Rockville, Maryland 20852-1448. It is also requested that distribution reports be submitted according to 21 CFR 600.81.

Please submit three (3) copies of final printed labeling at the time of use accompanied by Part II of FDA 2567 with completed implementation information. You may wish to submit additional advertising and promotional campaign material. If so, please submit three (3) copies of the proposed material in draft form with Part I of the Form FDA 2567/2253 to CBER, Advertising and Promotional Labeling Staff (APLS), HFM-602, 1401 Rockville Pike, Rockville, Maryland 20852-1448. Promotional claims should be consistent with and not contrary to the approved labeling. No comparative claims or claims of superiority over other similar products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research. Final copies of advertising and promotional materials should be submitted at the time of use with Part II of FDA Form 2567/2253 to APLS. Please include copies of the approved labeling with your proposed or final copy of advertising and promotional materials submitted to CBER.

Sincerely yours,

Jay S. Epstein, M.D.
Director
Office of Blood Research and Review
Center for Biologics
Evaluation and Research